

Federal Insecticide, Fungicide, and Rodenticide Act

What is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)?

FIFRA is the principal law that authorizes EPA to regulate the manufacture, distribution, sale, and use of pesticides in the United States. EPA determines that a pesticide meets FIFRA health and safety requirements, and then approves a product label that identifies the terms for safe use of the pesticide. EPA has authority under FIFRA to regulate pesticide use through labeling, packaging, composition, and disposal. EPA also has authority to suspend or cancel pesticide registration if new information shows that continued use of the pesticide would pose unreasonable risks. (For the complete text of FIFRA, see www.epa.gov/opp00001/regulating/fifra.pdf.)

States are also authorized to regulate pesticides under FIFRA and state pesticide laws. (For the text of Federal regulations regarding state pesticide registrations, see 40 CFR Part 162 www.access.gpo.gov/nara/cfr/waisidx_04/40cfr162_04.html). States may place more restrictive requirements on pesticides than does EPA. Contact information for state pesticide regulatory agencies can be found at <http://npic.orst.edu/state1.htm>.

In particular, FIFRA Sections 18 and 24(c) might apply to AIS rapid response or control activities. Section 18 applies to use of a pesticide for an unregistered use, and Section 24(c) applies to new uses or new end use products.

Parrot feather watermilfoil
Myriophyllum aquaticum

Pesticides are often understood to be just bug sprays or weed killers, but they include almost all substances or mixtures intended to kill or repel pests, prevent their reproduction, or mitigate or control their behavior or life-patterns. They include repellents and bactericides, as well as insecticides, herbicides, and fungicides.

Flathead catfish
Pylodictus olivaris

FIFRA Section 18—Emergency Exemptions

What is FIFRA Section 18?

FIFRA Section 18 authorizes EPA to allow states to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. (For more information about FIFRA Section 18 emergency exemptions, see www.epa.gov/opprd001/Section18. For the text of Federal regulations regarding emergency exemptions, see 40 CFR Part 166 www.access.gpo.gov/nara/cfr/waisidx_04/40cfr166_04.html.)

When does FIFRA Section 18 apply to AIS rapid response or control actions?

AIS rapid response or control methods using pesticides must comply with FIFRA and the regulations promulgated thereunder. If a pesticide is already registered for the rapid response or control use under FIFRA, the action does not require additional permitting from EPA. There are several pesticides registered for use in aquatic environments, and natural resource managers may be able to rely on these pesticides to eradicate or control AIS. If the rapid response or control action requires the use of an unregistered pesticide or a pesticide registered for a different end use or use pattern and an emergency situation exists, Federal or state agencies may be able to obtain approval to use an unregistered, i.e. nonlabeled, pesticide under FIFRA Section 18.

Emergency exemptions are subject to EPA's regulations at 40 CFR Part 166. A general summary follows.

An emergency condition is an urgent, nonroutine situation that requires the use of a pesticide or pesticides and meets the following criteria:

- no effective registered pesticides are available
- no feasible alternative control practices are available
- the situation involves the introduction of a new pest, will cause significant economic loss, or will present significant risks to human health, endangered species, or the environment

Detection of an AIS can qualify as an emergency condition. Natural resource managers considering use of an unregistered pesticide or a pesticide registered for a different end use or use pattern to eradicate or control AIS should consult their lead state agency for pesticides about the possibility of developing a Section 18 emergency exemption application. Contact information for state pesticide regulatory agencies can be found at <http://npic.orst.edu/state1.htm>.



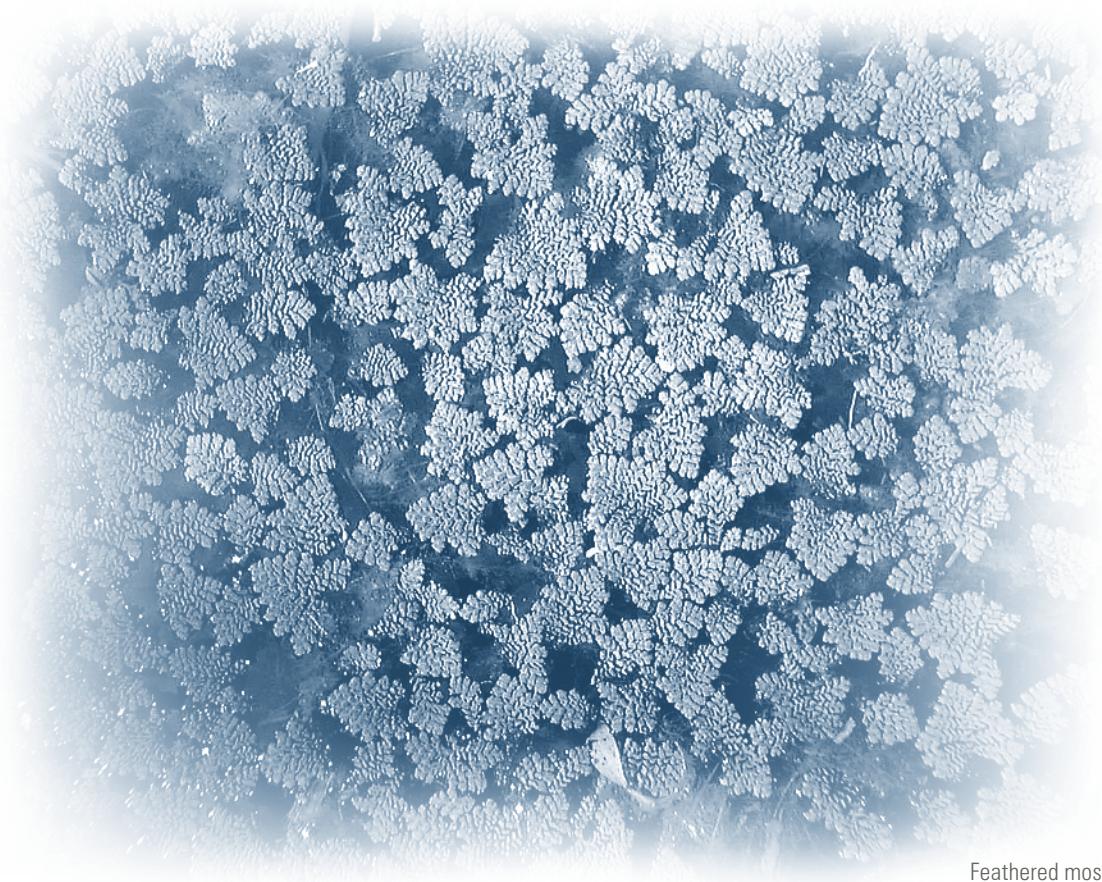
Water lettuce
Pistia stratiotes

How do I apply for a FIFRA Section 18 Emergency Exemption?

Lead state agencies can develop applications for several categories of emergency exemptions:

- specific exemptions are issued to avert significant economic loss or a significant risk to endangered or threatened species, beneficial organisms, or the environment
- quarantine exemptions are issued to control the introduction or spread of a new or currently localized pest
- public health exemptions are issued to control a pest that poses a significant risk to human health
- crisis exemptions are issued in instances when the time between discovery of the emergency and the time when pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption

Quarantine exemptions are generally the most appropriate for AIS rapid response and control actions. Crisis exemptions may be appropriate when actions need to be taken extremely quickly (i.e. within a matter of days or weeks).



Feathered mosquito fern
Azolla pinnata

Specific, Quarantine, or Public Health Emergency Exemptions

EPA has developed regulations and guidance documents that describe the data necessary to apply for a Section 18 exemption. A specific, quarantine, or public health emergency exemption application must provide the following information:

1. the type of exemption requested and the identity of contact persons
2. a description of the pesticide and complete labeling for proposed exemption use
3. a description of the proposed use
4. alternative methods of control
5. the effectiveness of the proposed use
6. residue in food or feed use
7. a discussion of risk information
8. coordination with other affected Federal or state agencies
9. notification of basic manufacturer or registrant
10. compliance and enforcement program for any special requirements
11. repeated uses
12. progress toward registration, if applicable

Quarantine exemption applications must provide the following additional information:

13. scientific and common name of the pest
14. origin of the pest and the means of its introduction, if known
15. anticipated impact of the pest
16. impact of the pest if uncontrolled
17. pertinent information about the potential economic impacts of the pest

EPA attempts to make decisions about the exemption within 50 days of receiving a completed application. During this period, EPA conducts dietary, occupational, and environmental risk assessments of the requested use. EPA also assesses the emergency situation and the progress toward permanent pesticide registration for the use in question, if applicable. Some emergency exemptions require public notification.

If EPA determines that the risks posed by the proposed use of the pesticide are acceptable and that the criteria for an emergency condition have been met, EPA approves the emergency exemption request. If the proposed



Brazilian waterweed
Egeria densa

pesticide use may cause unreasonable adverse effects to health or the environment, or if the emergency exemption criteria are not met, EPA will deny the emergency exemption request. Section 18 emergency exemptions are typically utilized for pesticides that are already registered under FIFRA for other uses. Quarantine exemptions can be approved for up to 3 years, whereas other exemptions may only be approved for up to 1 year.

Crisis Exemptions

Crisis exemptions are used in dire situations when an emergency exists, the time period for pesticide application is critical, and there is insufficient time to request another type of exemption. A crisis exemption allows for the use of an unregistered pesticide for up to 15 days. If the Federal or state agency submits or has already submitted an application for a specific, quarantine, or public health exemption for the same use, use of the unregistered pesticide under the terms of a crisis exemption may be allowed to continue until EPA makes a decision on the exemption application.

A crisis exemption request may be issued by the head of a Federal or state agency, the Governor of a state, or their official designee. Whenever feasible, the Federal or state agency issuing the crisis exemption must notify EPA of this action at least 36 hours prior to using the crisis provisions. The notification provided to EPA must contain:

1. the name of the active ingredient and Chemical Abstract Service (CAS) number
2. the site or crop on which the pesticide is to be used
3. the use pattern
4. the approximate start and end date of application
5. an estimate of the expected pesticide residue level for food crops
6. a discussion of the emergency situation and any other pertinent information available at the time, including an explanation of why there was insufficient time to request another type of exemption

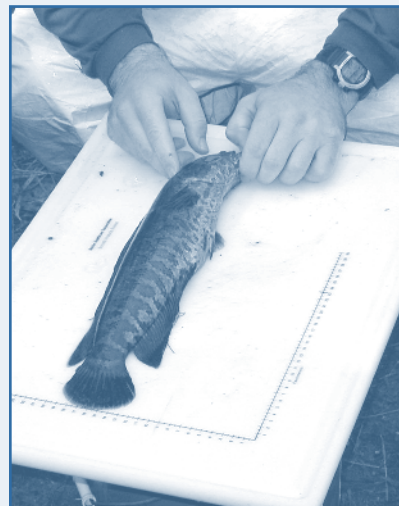
EPA reviews the notification package to ensure that all required information has been made available and that the use of the pesticide under the crisis exemption conditions will not pose an unreasonable risk to health or the environment. Notification must also be given to the registrant or the manufacturer of the pesticide. Crisis exemptions may not be utilized for pesticides that have been suspended under FIFRA Section 6(c), pesticides containing a new active ingredient, or the first food use of a pesticide. Neither are they issued to mitigate emergencies for which crisis exemptions or specific exemptions have been issued in previous years.



Old World climbing fern
Lygodium microphyllum

FIFRA Section 18 Case Study: Eradicating Northern Snakeheads in Crofton, Maryland Ponds

On May 18, 2002, a recreational angler caught an 18-inch fish in a small pond in Crofton, Maryland, which is located between Baltimore, MD and Washington, DC. He photographed the fish and released it back into the pond. A month later, the Maryland Department of Natural Resources (MD DNR) identified the fish as a species of snakehead. In the following two months, a second adult snakehead (26 inches long) and over 100 juveniles were caught in the same pond and identified as northern snakehead *Channa argus*. Northern snakeheads are large, predatory fish native to China. They can grow to 3 feet in length and primarily eat other fish, including fish up to one-third their length. They can breathe air and survive out of water if kept moist and cool. They cannot walk, as is commonly reported, but are easily shipped alive or transported by people. MD DNR conducted an investigation to determine the source of the snakeheads in the Crofton pond and learned that in 2000, a local resident had released two 12- to 14-inch northern snakeheads into the pond.



Immediately after the fish were positively identified and determined to be a risk to local ecosystems, the Secretary of the MD DNR (Secretary) assembled the Snakehead Scientific Advisory Panel (Panel) to develop strategies for eradicating and controlling the fish in the Crofton pond. On July 29, 2002, the Panel presented the Secretary with a list of risks the northern

snakehead posed to natural resources. It recommended chemical eradication of the Crofton pond vegetation and fish populations, along with those of two small adjacent ponds, to prevent the spread of the fish to the Little Patuxent River. Chemical eradication of vegetation would remove potential refuges for the fish and facilitate application of the piscicide rotenone.



The herbicides glyphosate and diquat bromide were chosen to eliminate emergent and submerged pond vegetation. After removal of the vegetation, application of the piscicide rotenone would effectively eradicate

the northern snakeheads in the ponds. These chemicals were chosen for their effectiveness and relatively rapid decomposition after application. The Panel recommendation to control vegetation in the entire pond area in one application exceeded the manufacturer's label restriction for a maximum 50 percent areal application and therefore did not meet Maryland Department of Environment (MD DE) standards. Because the proposed diquat bromide application differed from allowable use patterns and the available label for diquat bromide, the MD DNR worked with the Maryland Department of Agriculture (MD DA), the lead state agency for pesticide registration, to submit a FIFRA Section 18 emergency exemption application.

Quarantine exemptions are generally the most appropriate exemptions for AIS rapid response actions requiring Section 18 emergency exemptions. However, the potential for spread of the northern snakehead to other water bodies and the potentially devastating environmental impacts of such a spread led the MD DNR and MD DA to apply for a crisis exemption because those programs can be initiated immediately after the lead state authority declares a crisis situation. EPA reviews the crisis on an expedited basis, but use of the pesticide may begin once the lead state agency has invoked its authority to initiate a crisis program.

In the Crofton ponds case, effective interagency collaboration and communication resulted in the timely and successful preparation of a Section 18 emergency exemption application. The application was prepared by the MD DA Pesticide Coordinator with support from the MD DNR and the EPA Section 18 program. MD DA submitted the application package to EPA on August 1. The following day, EPA requested confirmation of the pesticide registration number (EPA's records showed that two pesticides with the same active ingredient were registered) and additional information regarding steps that would be taken to ensure that fish from the treated ponds would not be used for human consumption. On August 6, EPA granted a Section 18 crisis exemption for the proposed use of diquat bromide in the three Crofton ponds for up to 15 days.

State officials faced an additional obstacle to herbicide application in the Crofton ponds, however, because the ponds were on private property and the State lacked the statutory authority to access the property. Permission to access the property was eventually obtained from the owners, and the diquat bromide was applied before the end of the 15-day crisis exemption period. After the application of herbicides and a piscicide took place, over 1000 juvenile and six adult northern snakeheads were recovered. Approximately 800 pounds of native fish were also removed from the three ponds.



In late September and November 2002, state biologists used electro-shock monitoring in all three ponds and determined that no northern snakeheads remained in the ponds. Vegetation returned the following spring, and MD DNR stocked the ponds with native fish. Turtles, frogs, snakes, ducks, and beavers appear to have been unaffected by the pesticides.

In 2004 and 2005, northern snakeheads were found in several other water bodies in the region. These fish are believed to be the result of separate introductions rather than the spread of the species from the Crofton ponds.

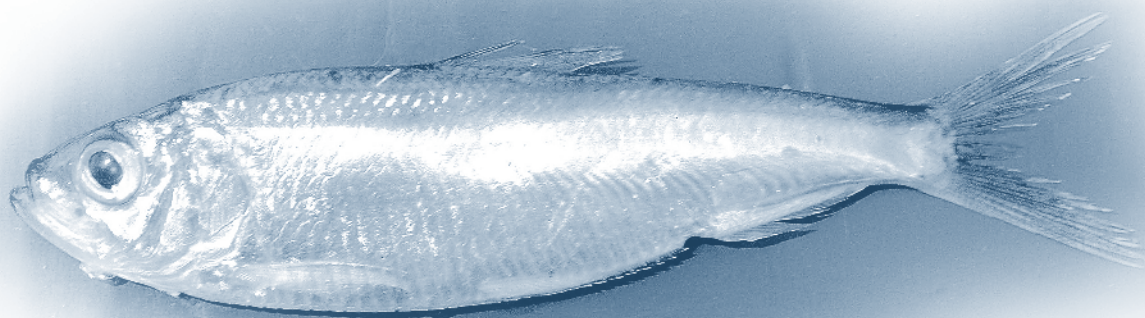
FIFRA Section 24(c)—Special Local Need Registrations

What is FIFRA Section 24(c)?

FIFRA Section 24(c) authorizes states to register an additional use of a Federally-registered pesticide product or a new end use product to meet a special local need. (For EPA guidance on FIFRA Section 24(c) registrations, see www.epa.gov/opprd001/24c.)

When does FIFRA Section 24(c) apply to AIS rapid response or control actions?

AIS rapid response or control methods using pesticides must comply with FIFRA and the regulations promulgated thereunder. If a pesticide is already registered for the rapid response or control use under FIFRA, the action does not require additional permitting from EPA. There are several pesticides registered for use in aquatic environments, and natural resource managers may be able to rely on these pesticides to eradicate or control AIS. If the rapid response or control action requires the use of an unregistered pesticide or a pesticide registered for a different end use or use pattern and a state can demonstrate a special local need, FIFRA Section 24(c) authorizes a state to register an additional use of a Federally-registered pesticide product. Section 24(c) registrations are also referred to as state labels or special local need registrations and are considered Federal registrations authorizing distribution and use within the granting state only.



Alewife
Alosa pseudoharengus

State registrations under Section 24(c) are subject to EPA's regulations at 40 CFR Part 162. A general summary follows.

States may register a new use or use pattern of a Federally-registered pesticide if all of the following conditions exist:

- There is a special local need for the use within the state. A special local need is an existing or imminent pest problem within a state for which the state has determined that an appropriate Federally-registered pesticide is not sufficiently available.
- If the pesticide use is a food or feed use, there must exist appropriate tolerances (maximum amount of pesticide residue allowed in or on a food or feed commodity) or exemptions from the requirement of a tolerance under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). If these tolerances do not already exist, a Section 24(c) registration cannot be used, and a Section 18 emergency exemption may be more appropriate. Under FFDCA Section 408, EPA may establish a temporary tolerance or exemption from the tolerance requirement for a Section 18 emergency exemption.
- Registration for the same use has not previously been denied, disapproved, suspended or canceled by EPA, or voluntarily canceled by the registrant subsequent to EPA issuing a notice of intent to cancel that registration because of health or environmental concerns, unless such denial, disapproval, suspension or cancellation has been superseded by a subsequent EPA action.
- The registration is in accord with the purposes of FIFRA.



Nutria
Myocastor coypus

How do I apply for a FIFRA Section 24(c) Registration?

Each state designs its own review process and timeline for state pesticide registration. As part of its review process, each state is required to conduct an ecological risk assessment (ERA) to determine if the pesticide will cause unreasonable adverse effects on humans or the environment under the following circumstances:

- the pesticide's composition is not similar to any Federally-registered pesticide
- the use of the pesticide is not similar to any Federally-registered use of the same pesticide or a pesticide of similar composition
- EPA has denied, disapproved, suspended, or canceled registration of other uses of the same pesticide or uses of pesticides of similar composition

All products registered by a state must meet all appropriate packaging standards and might need to be classified as restricted use if their toxicity exceeds EPA specific hazard criteria. Depending on the length of time needed to conduct an ERA, Section 24(c) pesticide registrations requiring an ERA may be more useful for ongoing control of AIS rather than for carrying out AIS rapid response actions.



Brazilian peppertree
Schinus terebinthifolius

If a state decides to issue a Section 24(c) registration, it must send EPA a notification package within 10 days of issuing a registration containing the following:

- an application for the Section 24(c) registration
- verification of a special local need
- if required, a determination of no unreasonable adverse effects on humans or the environment
- verification of efficacy for public health uses
- the original registered labeling and the Section 24(c) labeling of the pesticide; and
- notification of state pesticide registration describing:
 - tolerances or clearances for food or feed use
 - type of registration, i.e. new pesticide or changed use pattern
 - history of previous Section 24(c) activity or registration for the pesticide
 - list of threatened or endangered species within use area of pesticide

EPA has 90 days to verify that the special local need registration meets FIFRA requirements. If EPA subsequently disapproves the registration, sales and distribution must stop immediately.



Parrot feather watermilfoil
Myriophyllum aquaticum

FIFRA Section 24(c) Case Study: Controlling Old World Climbing Fern in Florida

Old World climbing fern *Lygodium microphyllum* is an aggressive perennial vine that has invaded cypress stands, pine flatwoods, wet prairies, sawgrass marshes, mangrove communities, and Everglade tree islands in Florida. The vine can reach 90 feet in length and form dense mats in tree canopies, on the ground, and over wetlands, killing native vegetation. The first reported occurrence of Old World climbing fern in Florida was a plant in cultivation at a Delray Beach nursery in 1958. In 1960, the vine was observed in the wild in Martin County. Old World climbing fern eventually became a severe threat to native Florida ecosystems, especially cypress-dominated wetlands, and in the 1990s, the South Florida Water Management District (SFWMD) began evaluating methods of controlling the vine, including herbicides, fire, flooding, physical removal by hand or machinery, and biological controls.



Aerial spraying of herbicides is one of the most effective means of controlling invasive plants in remote or otherwise inaccessible areas, but may involve the application of herbicide directly to water. Old World climbing fern had invaded many remote and inaccessible areas in Florida, and aerial spraying was desired to control the vine in those areas. At the time, the most effective product for controlling the vine registered for direct application to water was the glyphosate-based herbicide Rodeo™, a broad spectrum herbicide that injures or kills many nontarget species. To avoid harming other vegetation in Old World climbing fern-infested areas, SFWMD sought alternatives to Rodeo. The District found that application of the herbicide Escort XP™, a metsulfuron methyl-based product, directly to water showed promise as an effective means to control the vine. The application of Escort XP directly to water was not a registered use for the product and was therefore not in compliance with FIFRA. To use Escort XP for vine control, the SFWMD pursued a Section 24(c) special local need registration for the herbicide.

Florida natural resource managers wishing to control invasive plants often informally consult weed management experts at the University of Florida Institute of Food and Agricultural Science (IFAS) to determine optimal control methods. The SFWMD contacted IFAS about the Old World climbing fern, and in April 2003, IFAS informally contacted the DuPont Corporation, the manufacturer of Escort XP, about using the herbicide to control Old World climbing fern in aquatic



ecosystems. In Florida, pesticide manufacturers generally begin the Section 24(c) special local need registration process on behalf of natural resource managers who want to use one of their pesticide products for a new use or use pattern. Consequently, in May 2003, DuPont submitted a Section 24(c) special local need registration application to the Florida Department of Agriculture and Consumer Services (DACS), the lead state agency for pesticide registration. Section 24(c) special local need registration applications in Florida must include verification of the product's efficacy under Florida or Florida-like conditions, as well as the information described in the FIFRA Section 24(c) section of this document.

After DACS received the Section 24(c) special local need registration application, it reviewed the application to verify the special local need justification. In June 2003, DACS forwarded the application to the Florida Pesticide Registration Evaluation Committee (PREC), which is comprised of representatives from DACS and other state agencies. PREC reviewed the Section 24(c) special local need registration application to ensure that the proposed herbicide use would not have unreasonable adverse impacts on human health or the Florida environment and was in compliance with all applicable pesticide laws. PREC requested that DuPont make several revisions to the Escort XP Section 24(c) special local need label. After these revisions were made, the application was submitted to IFAS for independent external review of whether product label efficacy claims were justified. Three IFAS weed management experts offered individual opinions on the Escort XP efficacy claims. On the basis of these opinions, IFAS responded to DACS that it supported the Section 24(c) special local need registration of the herbicide but also requested additional changes to the product label.

In Florida, the Section 24(c) special local need registration application review process can take anywhere from a few months to over a year. In this case, the process was completed quickly. DACS accepted DuPont's Section 24(c) special local need registration with the revised label and submitted a notification package to EPA in August 2003. EPA also requested revisions to the Escort XP Section 24(c) special local need label, including the addition of a section prohibiting the use of the herbicide in areas where specific endangered or threatened species are present. In December 2003, DACS accepted the revised product label. The herbicide is now available for controlling Old World climbing fern populations in aquatic environments in Florida.

